

**REMARKS**

Claims 1-66 are pending. Claims 28-66 have been cancelled as being directed to a non-elected invention. Applicant reserves the right to pursue these claims in a later filed application which claims priority to the subject application. Following entry of the amendment claims 1-27 will be pending and under examination.

Applicant wishes to thank Examiners Arnold and Richter for extending the personal interview conducted on May 7, 2007, to Applicant and his representative. During that interview the obviousness rejections over Kosbab, US 2001/0031744 and over Gorsek, U.S. Patent No. 6,103,756 and Ames et al., U.S. Patent No. 5,916,912 set forth in the Office Action mailed February 12, 2007, were discussed. Evidence directed to the unexpected results of the claimed invention was presented and viewed favorably by the Examiners. This evidence is submitted herewith and requested to be made of record.

Applicant acknowledges withdrawal of the final Office Action mailed February 12, 2007, and issuance of the current Office Action, mailed May 16, 2007, in lieu thereof.

**Rejections Under 35 U.S.C. § 102**

Claims 1, 4, 5, 6 and 9 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by Barker et al., WO 00/76492. The Office alleges that Barker et al. describe a combination of nutrients including: vitamin E (50-500 IU); vitamin C (60-500 mg); selenium (20-300 µg); N-acetyl-L-cysteine (500-2000 mg); curcumin (5-50 mg); mixed polyphenols (500-1500 mg green tea extract), and mixed carotenoids (500-2000 mg mixed vegetable extract) and concludes that carotenoids, polyphenols and N-acetyl-L-cysteine correspond to three high potency antioxidants.

When lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349, 48 U.S.P.Q.2d 1225, (Fed. Cir. 1998) (quoting *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d 1133, 1136 (Fed. Cir. 1992)). To establish a *prima facie* case of anticipation, the Office must show that the single reference cited as anticipatory art describes all the elements of the claimed invention.

The Office has failed to meet this burden because carotenoids, polyphenols and N-acetyl-L-cysteine do not constitute three high potency antioxidants as described and claimed by the invention.

Applicant claims a nutrient composition which includes at least three high potency antioxidants. The application defines a high potency antioxidant to mean a “non-vitamin or non-mineral antioxidant” (paragraph 025). Carotenoids and the common antioxidant activity of polyphenols are vitamin antioxidants. Therefore, two of the compounds described by Barker et al. which are alleged to be high potency antioxidants do not fall within the definition of the term.

Carotenoids are a class of highly unsaturated pigments which include carotenes. *Webster's Third New International Dictionary, Unabridged*. Merriam-Webster, 2002. <http://unabridged.merriam-webster.com> (14 Jun. 2007). Carotenes include any of three orange or red crystalline pigments known as  $\alpha$ -,  $\beta$ - and  $\gamma$ -carotene which have a  $C_{40}H_{56}$  structure and are convertible in the animal body to vitamin A. *Id.* Moreover, the application specifically teaches that carotenoids are vitamin antioxidants when it explicitly states:

Beta-carotene is a vitamin antioxidant that also is convertible to vitamin A in the liver of animals.

Application at para. 045 (emphasis added); *see also*, para. 029 (“[t]he at least one vitamin antioxidant can be . . . beta-carotene”), and para. 040 (“vitamin antioxidants that can be selected . . . include . . . beta-carotene”).

In light of the definitions above and the explicit classification of  $\beta$ -carotene in the application as a vitamin antioxidant, the carotenoids in the purported formulation of Barker et al. cannot constitute a high potency antioxidant because carotenoids are vitamins. Therefore, Barker et al. cannot anticipate the invention as claimed because Barker et al. does not describe three high potency antioxidants which are non-vitamin or non-mineral antioxidants.

Polyphenols also do not fall into the definition of a high potency antioxidant as described and claimed by Applicant. Polyphenols are a group of chemical substances having more than one phenol group per molecule and include flavonoids, tannins and phenylpropanoids. *Wikipedia*, Wikipedia Foundation, Inc., 2007. <http://en.wikipedia.org/wiki/Polyphenol> (14 June

2007). Within this group, flavonoids, or bioflavonoids, are most commonly known for their antioxidant activity (*Wikipedia*, <http://en.wikipedia.org/wiki/Flavonoid> (14 June 2007)) and also are known as vitamin P (*Webster's Third New International Dictionary, Unabridged*. Merriam-Webster, 2002. <http://unabridged.merriam-webster.com> (14 Jun. 2007)). Further, the application specifically teaches that bioflavonoids are vitamin antioxidants when it explicitly describes:

The at least three vitamin antioxidants can be three vitamins selected from . . . bioflavonoid complex.

Application at para. 090; *see also*, para. 029 (“[t]he at least one vitamin antioxidant can be . . . bioflavonoid complex”).

In light of the definitions above and the explicit classification of bioflavonoids in the application as a vitamin antioxidant, the polyphenols in the purported formulation of Barker et al. cannot constitute a high potency antioxidant because the commonly known antioxidant component of polyphenols are vitamins. Therefore, Barker et al. cannot anticipate the invention as claimed because Barker et al. does not describe three high potency antioxidants which are non-vitamin or non-mineral antioxidants.

In view of both canotenoids and polyphenols constituting vitamin antioxidants, Barker et al. cannot anticipate the claimed invention. Therefore, withdrawal of this ground of rejection is respectfully requested.

### **Rejections Under 35 U.S.C. § 103**

Claims 1-27 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kosbab, U.S. Patent Application 2001/0031744. Conceding that Kosbab fails to disclose a nutrient composition containing highly saturable amounts of at least three high potency antioxidants, the Examiner cites to Table 3, which is alleged to show dosage ranges for a wide variety of compounds, and Table 4, which is alleged to show an exemplary nutrient formula, to conclude that it would have been obvious to combine three high potency antioxidants in highly saturable amounts. The motivation to do so is allegedly because Kosbab “provides the preferred dosage ranges of formula components such that one of ordinary skill in the art could reduce to practice

the instant invention by: 1) adding highly saturable amounts of at least 3 high potency antioxidants” (Office Action, p. 5, para. 2).

To establish a *prima facie* case of obviousness, the Office must show that the prior art would have suggested the claimed invention to one of ordinary skill in the art and that it could have been carried out with a reasonable likelihood of success when viewed in the light of the prior art. *Brown & Williamson Tobacco v. Philip Morris*, 229 F.3d 1120, 1124 (Fed. Cir. 2000), accord *In re Royka*, 180 USPQ 580 (C.C.P.A. 1974) (to establish *prima facie* obviousness, all claim limitations must be taught or suggested by the prior art); M.P.E.P. §2143.03.

As Applicant and his representative articulated in the personal interview conducted May 7, 2007, the above rejection fails to meet the required burden because no reason is stated as to why there is a teaching, suggestion or motivation to arrive at the claimed combination of three high potency antioxidants in highly saturable amounts. The proffered reason that Kosbab lists preferred dosage ranges for many different compounds appears conclusory because it merely restates the facts alleged by the Examiner, namely, that there’s a list of dosages. A mere list of dosages does not provide a teaching or suggestion or a reason why one of ordinary skill would be motivated to select and combine three high potency antioxidants from a list of 70 diverse compounds and combine them in highly saturable amounts. Hence, absence some reason why one skilled in the art would have arrived at the claimed three high potency antioxidants in highly saturable amounts from a list of 70 different components, the Examiner has not established his burden for a *prima facie* case of obviousness.

Assuming *arguendo* that the Examiner has met his burden, the law is clear that there must be a teaching, suggestion or motivation to arrive at the claimed invention. As articulated by the court in *Pfizer v. Apotex, Inc.*, Case No. 2006-1261 (Fed. Cir., March 22, 2007), selection of components from an indefinite list constitutes a promising field of experimentation. Such selection is unobvious and is not comparable to varying known parameters from a finite list with the expectation that one of the varied parameters will work. Here, Kosbab describes Formulas IA-K, Formulas IIA-G, with at least 12 additional formulas set forth at paragraphs 0146-0162; Formulas IIIA-F, with at least eight additional formulas set forth at paragraphs 0222-0230; Formulas IVA-E, with at least six additional formulas set forth at paragraphs 0288-0294, and

Formulas VA-H, with at least six additional formulas set forth at paragraphs 0352-0358. All of these formulas consist of a heterogeneous mixture of numerous, diverse compounds with no apparent rationale for any selection of high potency antioxidants nor for a combination of three high potency antioxidants in highly saturable amounts. A summary of the formulas and their distinctions over Applicant's claimed invention was set forth in Applicant's previous response and is reasserted here for reconsideration (Supplemental Response filed September 20, 2006, at p.15, para. 1 through p.16, para. 4). Kosbab additionally lists dosage ranges for 70 different compounds in Table 3. The total number of combinations of five distinct antioxidants from such a list results in 11,238,513 possible formulations.

From this large number of different possible formulations one of ordinary skill in the art would not arrive at the claimed combination of three high potency antioxidants in highly saturable amounts (plus one vitamin antioxidant and one mineral antioxidant) because there are too many combinations to choose from with no teaching, suggestion or reason why which parameters should be varied. The list further fails to teach or suggest which components constitute high potency antioxidants and why one of ordinary skill in the art should combine at least three. There also is no teaching or suggestion as to what constitutes a highly saturable amount of a high potency antioxidant. Rather, Kosbab is directed to vascular and capillary disorders. A nutrient composition to these disorders would not motivate one to arrive at the claimed composition for enhancing immune function. Absent some teaching or suggestion for these claimed elements or some reason why one of ordinary skill should select at least three high potency antioxidants for combination in highly saturable amounts, the lists and recitation of Formulas IA-K, IIA-G, IIIA-F, IVA-E and VA-H in Kosbab is a mere invitation to experiment.

The above conclusion is supported by Table 4 in Kosbab because Kosbab chooses to provide an exemplary formulation. However, the exemplified formulation fails to include highly saturable amounts of three high potency antioxidants. Rather, Co-enzyme Q10 and lipoic acid are both formulated in amounts of 20 mg/day, which is lower than the ranges of high potency antioxidants taught in the application.

In further support, Applicant presented Examiners Arnold and Richter with evidence of unexpected results of the claimed formulation having at least three high potency antioxidants in

highly saturable amounts over formulations lacking at least three high potency antioxidants in the claimed amounts. Attached as Exhibit A is a declaration by Dr. Jon D. Kaiser attesting that the claimed combination of at least three high potency antioxidants in highly saturable amounts provides synergistic and unexpected results. The declaration further attests to the commercial success of the claimed formulation. Such secondary indicia of nonobviousness are sufficient to rebut the purported *prima facie* case of obviousness.

In light of the above, Applicant respectfully requests that this ground of rejection be withdrawn.

Claims 1-27 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Gorsek, U.S. Patent No. 6,103,756, in view of Ames et al., U.S. 5,916,912 and Kosbab. Gorsek is alleged to describe a formula containing alpha lipoic acid, N-acetyl-cysteine, glutathione, vitamins A, B6, C and E, folic acid, zinc, selenium and bioflavonoids. The Examiner concedes that Gorsek fails to disclose the high potency antioxidant acetyl L-carnitine. Ames et al. is alleged to describe a formula having at least one antioxidant and acetyl L-carnitine for restoring mitochondrial function in older animals. Citing to Table 3, Kosbab is alleged to describe amounts of antioxidants to use in a formulation. The Office alleges that it would have been obvious to modify the composition of Gorsek with a highly saturable amount of acetyl L-carnitine as suggested by Ames et al. and Kosbab for the purpose of reversing the indicia of aging. Motivation for the combination is alleged to derive from the restoration of youth being a desirable health benefit and marketing feature.

As set forth previously and discussed during the personal interview with Examiners Arnold and Richter, the cited combination of references fails to render the invention obvious because these references provide nothing more than the mere identification of elements of Applicant's claimed invention. In particular, there is no teaching, suggestion or motivation in the cited combination, or generally known in the art, that would lead one of ordinary skill to combine three high potency antioxidants in highly saturable amounts.

As described previously, Kosbab fails to provide the requisite suggestion or motivation to combine three high potency antioxidants in highly saturable amounts because there is an indefinite list of combinations without any suggestion or reason to combine the claimed three

high potency antioxidants in highly saturable amounts. As previously made of record, Gorsek also describes a formula lacking three high potency antioxidants and also is without any apparent suggestion or reason to combine together more than one high potency antioxidant into a formulation or to combine them in highly saturable amounts. Ames et al. also cannot provide the suggestion or motivation as alleged by the Examiner because Ames et al. appears to be directed to the use of acetyl L-carnitine for a purpose different than augmenting immune strength or physiological detoxification. In particular, and as pointed out in Applicant's previous response, Ames et al. teach away from combining acetyl L-carnitine in other formulations for the purpose of increasing the metabolic rate of aged cells because Ames et al. describe that their formulation restored all mitochondrial functions and reversed gross indicia of aging. Therefore, Ames et al. teach that their formulation achieves its intended purpose and one of ordinary skill in the art would not be motivated to include additional antioxidants in the formulation of Gorsek nor include any of the amounts of Kosbab based on Ames et al. because Ames et al. teach that there is no need to do so. Accordingly, the cited combination fails to provide the required teaching, suggestion or motivation for one of ordinary skill to arrive at the claimed invention containing a saturable amount of at least three high potency antioxidants.

In addition, further support for the unobviousness of the claimed invention also can be found in the declaration submitted herewith as Exhibits A. As set forth previously, Exhibit A is a declaration by Dr. Jon D. Kaiser attesting that the claimed combination of at least three high potency antioxidants in highly saturable amounts provides synergistic and unexpected results. The declaration also attests to the commercial success of the claimed formulation. Such secondary indicia of nonobviousness are sufficient to rebut the purported *prima facie* case of obviousness.

In light of the above, Applicant respectfully requests that this ground of rejection be withdrawn.

Claims 1-27 stand further rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Barker et al. in view of Ames et al. and Kosbab. The cited references are applied as described above, with the admission that Barker et al. do not expressly teach a formulation containing alpha lipoic acid, acetyl-L-carnitine, co-enzyme Q10, glutathione, bioflavonoid

complex vitamin B6, beta-carotene and zinc. The Examiner concludes that it would have been obvious to one of ordinary skill to add the above components in the amounts suggested by Kosbab and Ames et al. to arrive at the claimed invention. One would have been motivated to do so allegedly because Barker et al. teach the addition of other active antioxidants and Kosbab et al. and Ames et al. cure the lack of which antioxidants to add by describing additional components.

Applicant respectfully points out that to establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (C.C.P.A. 1974); M.P.E.P. §2143.03.

As articulated, the above rejection fails to meet the Examiner's burden because not all elements are taught or suggested. In particular, the rejection appears to concede that Barker et al. fail to describe three high potency antioxidants in highly saturable amounts. Kosbab is cited for allegedly describing amounts of components and is summarily asserted to describe those "additional components to add to the composition." Office Action at p.9, para. 2. Ames et al. is similarly alleged to describe those "additional components to add to the composition." *Id.* However, as described previously, Kosbab fails to provide the requisite teaching or suggestion to combine three high potency antioxidants in highly saturable amounts and two of the asserted compounds in Barker et al. are not non-vitamin, non-mineral antioxidants. Ames et al. teaches away from any combination because this reference describes a formulation directed to acetyl L-carnitine that achieves its purpose. In further support, Applicant directs the Examiner's attention to the declaration attesting to the unexpected results and commercial success of the claimed invention (Exhibit A). Such secondary indicia of nonobviousness are sufficient to rebut the purported *prima facie* case of obviousness. Therefore, in light of the above, Applicant respectfully requests that this ground of rejection be withdrawn.

### **CONCLUSION**

In light of the Remarks herein, Applicant submits that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, he is invited to call the undersigned attorney.



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To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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